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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,751	12/21/2000	Mark N. Hochman	3486-018	1104

22440 7590 06/29/2005

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EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,751

Applicant(s)

HOCHMAN, MARK N.

Examiner

Michael J. Hayes

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 14-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/15/05 has been entered.

Applicant's papers submitted 4/15/05 listed claim amendments starting on page 2 and remarks starting on page 5. The submitted pages were marked as "Page 1 of 4" through "Page 4 of 4." No page 5 is present in the file and there is no record of remarks filed with the papers submitted 4/15/05.

Status of Claims

Applicant has canceled claims 1-13 leaving claims 14-23 currently in the application. Claims 14-23 were presented as new claims in paper received 9/30/04.

Claim Objections

Applicant should use appropriate claim status in a parenthetical expression following the claim number. Applicant's use of the phrase "currently reinstated" is not an acceptable claim status. See MPEP 714(II)(C).

Claim Rejections - 35 USC § 112

Claims 14-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitations added to the claims reciting a method of eliminating pain, eliminating pain-producing deflection, or preventing a needle from generating pain is new matter not originally disclosed in the specification as filed. The original specification mentions a method whereby "the amount of pain felt by the patient may be reduced." (abstract). This mention of a possibility to reduce pain does not provide a description of a method preventing or eliminating pain.

Claims 14-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's recitation of a method of eliminating pain, eliminating pain-producing deflection, or preventing a needle from generating pain is not enabled because Applicant has not provided a disclosure to enable one skilled in the art to use the method to provide painless needle deflection (or even reduced pain needle deflection) without undue experimentation. The claims are broadly recited with limitations to advancing a needle with simultaneous rotation to prevent pain from needle deflection. There is no description of the amount of deflection to avoid in order to prevent pain from any remaining deflection. The state of the prior art does not provide information in

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providing painless needle advancement so this is not an instance of Applicant not teaching what is well known in the art. The level of predictability in the art is very low because the subject matter is subjective pain in biological systems. Applicant has not provided any direction or working examples concerning the elimination of pain in advancing needles with reduced deflection. The quantity of experimentation would be large because of the biological variability and subjective nature of pain measurements. Because of these factors the examiner concludes that the method of eliminating pain, eliminating pain-producing deflection, or preventing a needle from generating pain, as recited in the claims is not enabled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 15, 17, and 19, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by BROWN (U.S. Patent No. 3,244,172). Brown discloses that it is well known in the art to turn or twist a beveled needle of a syringe while inserting it through tissue in methods of injecting. (1:15-23). This method will inherently eliminate pain during the syringe insertion because it makes the insertion easier with less tissue affected by the insertion.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN as applied to claims 14 and 19 above, and further in view of KUHLE (US Patent No. 5,938,635). Brown discloses that the insertion of a needle while rotating is known in the art. Brown does not disclose rotating a needle up to 180 degrees in one direction during insertion to reduce deflection. Kuhle discloses a method of advancing a needle while rotating to reduce deflection of the needle. Kuhle teaches a rotation of 360 degrees to balance forces, or alternatively several rotations of 180 degrees while advancing the needle. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kuhle in the method of Brown to recognize the desirability for accurately placing drug delivery needles and the established practice of rotating a needle during insertion.

Re claim 23 use of an advance rate of 2-4 mm/sec would be obvious to one of ordinary skill in the art as a design choice because Applicant has not stated that this advance rate serves any particular purpose or solves any stated problem and it appears that other advance rates would function equally as well. Applicant has not established any criticality to this advance rate.

Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN and further in view of Garnier (US Patent No. 4381777). Brown discloses the claimed

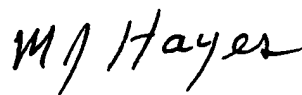
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invention except for rotating the needle in one direction, then the opposite direction as it is being advanced. Garnier teaches one directional and also bi-directional rotation (1:22-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Garnier in the method of Brown in order to avoid injury or breakage. One of ordinary skill in the art would recognize the advantages of Garnier's rotation in soft tissue because Garnier discloses rotation through the injection process which includes both soft tissue (i.e., porous bone) as well as harder bone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
25 June 2005


MICHAEL J. HAYES
PRIMARY EXAMINER